EMBLEM™ MRI S-ICD SYSTEM
Subcutaneous Implantable Defibrillator

System Specifications

The EMBLEM MRI S-ICD is the second device in the EMBLEM S-ICD family and builds on previous size, longevity and remote patient management enhancements. Unlike transvenous ICDs, the EMBLEM MRI S-ICD System utilizes a pulse generator capable of delivering life-saving therapy. Unlike traditional ICDs, the EMBLEM MRI S-ICD System leaves the heart and vasculature untouched, avoiding potential complications associated with transvenous leads.

The EMBLEM MRI S-ICD has been tested and approved for use in the MR environment when the conditions of use are met. It contains a separate MRI mode with a timer that will automatically return the device to programmed settings. AF Monitor™ has also been added. This is a tool designed to assist in the detection of new onset, silent, or the progression of AF through R-R variability. The new SMART Pass filter is designed to reduce cardiac over-sensing and bench testing has demonstrated a >40% reduction in inappropriate therapy.

Pulse Generator Specifications\(^1\,^2\)

**Mechanical Specifications**

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model Number</td>
<td>A219</td>
</tr>
<tr>
<td>Size (W x H x D)</td>
<td>83.1 x 69.1 x 12.7 mm</td>
</tr>
<tr>
<td>Mass</td>
<td>130g</td>
</tr>
<tr>
<td>Volume</td>
<td>59.5 cc (cm³)</td>
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<tr>
<td>Longevity</td>
<td>7.3 years(^*)</td>
</tr>
<tr>
<td>Battery</td>
<td>Boston Scientific Li/MnO(_2)</td>
</tr>
<tr>
<td>Device C-Code</td>
<td>C1722</td>
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</tbody>
</table>

NEW ImageReady™ MR-Conditional Technology

- Compatible Electrodes: 3400, 3401
- Magnet Strength: 1.5T
- Specific Absorption Rate (SAR) limits for the entire active scan (Normal Operating Mode):
  - Whole body averaged, < 2.0 watts/kilogram (W/kg)
  - Head, < 3.2 W/kg
- There are no anatomical exclusion zones or time restrictions.

Programmable Parameters

- Shock Zone: 170 bpm - 250 bpm (steps of 10 bpm)
- Conditional Shock Zone: Off, On 170 bpm - 240 bpm (minimum 10 bpm less than Shock Zone)
- S-ICD System Therapy: Off, On
- Post-shock pacing: Off, On (50 ppm, max 30 sec, demand-based)
- Induction capability: 1-10 sec (50 Hz/200 mA)
- Delivered Energy: 80J biphasic (only programmable during manual shock and induction test: 10J - 80J, steps of 5J)
- Shocks per episode: Maximum of 5 shocks

Diagnostic Tools

- **AF Monitor**: Information Provided:
  - Number of days with measured AF in the last 90 days
  - Estimate of measured AF in the last 90 days (%)
  - Performance: Sensitivity >= 87%  Positive Predictive Value >=90%
- Episode storage: S-ECG storage for over 40 arrhythmic events (treated & untreated)
- Other data: Electrode impedance, System status (remaining battery life, patient alerts, etc.), Date and time stamp

NOTE: Longevity projections and the associated energy consumption is based on bench testing only.

Specifications

Model Number | 3401
Type | Tripolar
Length | 45 cm
Distal tip size (Diameter) | 12 Fr/4 mm
Coil size (Diameter) | 9 Fr/3 mm
Electrode shaft size (Diameter) | 7 Fr/2.33 mm
Sensing surface area | Distal 36 mm², Proximal 46 mm²
Sensing location | Distal Electrode at tip, Proximal 120 mm from tip
Defibrillation surface area | 750 mm²
Defibrillation location | 20 - 100 mm from tip

Materials
- Insulation: Polyurethane
- Electrodes: MP35N
- Conductors: MP35N
- Connector pin: MP35N
- Suture Sleeve: Silicone
- Electrode C-Code: C1896

EMBLEM™ MRI S-ICD System from Boston Scientific CRM

Indications for Use
The S-ICD System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.

Contraindications
- Unipolar pacing and impedance-based features are contraindicated for use with the S-ICD System.
- Symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.

Specifications

- Electrode C-Code
- Suture Sleeve
- Connector pin
- Conductors
- Sense Loop
- Sensing location
- Defibrillation location
- Electrodes
- Insulation
- Electrode shaft size (Diameter)
- Distal sensing surface area
- Proximal sensing surface area
- Electrode shaft size (Length)
- Distal sensing location
- Proximal sensing location
- Defibrillation surface area
- Defibrillation location
- Materials
- Model Number
- Type
- Length
- Distal tip size (Diameter)
- Coil size (Diameter)
- Electrode shaft size (Diameter)
- Sensing surface area
- Sensing location
- Defibrillation surface area
- Defibrillation location
- Electrode C-Code

Precautions
- For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, and supplemental precautionary information.
- Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.
- Potential Adverse Events
- Patients who receive an S-ICD System may develop psychological disorders that include, but are not limited to, the following: depression/anxiety, fear of device malfunction, fear of shocks, phantom shocks.
- For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide. Rx only.

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